Point-of-Injury Care in Expeditionary Medicine

CDR James Patrey, Ph.D., MSC, USN
Deputy for Force Health Protection
Office of Naval Research
Arlington, VA 22203
USA
Voice (703) 696-0407 / Fax (703) 696-0332

james.patrey@navy.mil

William F. Sobotka III
Support Staff, Force Health Protection
Office of Naval Research
Arlington, VA 22203
USA
Voice (703) 588-2932 / Fax (703) 696-0332

william.sobotka.ctr@navy.mil

Dr. Judith Lytle
Support Staff, Force Health Protection
Office of Naval Research
Arlington, VA 22203
USA
Voice (703) 588-4715 / Fax (703) 696-0332

judith.lytle.ctr@navy.mil

Dr. Susan Kayar
Support Staff
Force Health Protection
Office of Naval Research
Arlington, VA 22203
USA

susan.kayar.ctr@navy.mil

ABSTRACT

The Office of Naval Research (ONR) is engaged intensively in the research of technologies that will ultimately provide superior combat casualty care to front-line care givers. Current tactical operations and future predicted operations will continue to rely on the concept of distributed operations supported by combat infantry and special operations units. These units will continue to be dispersed far from traditional logistic support bases and tails; to include compensatory medical support. As a result, front-line care givers, those critical independent corpsmen will continue to play an integral and vital role in sustaining quality combat casualty care. It is therefore imperative that organizations such as ONR, in unison with the Navy Bureau of Medicine (BUMED), Navy Expeditionary Combat Command (NECC), and Marine Corps System Command (MCSC), continue to deliver medical life sustaining technologies. Technologies currently being pursued by ONR include strategies and techniques for effective combat casualty care treatments, medical planning tools to support combat operations, and mechanisms to provide rapid non-invasive diagnoses.

TREATMENT

Control Internal Haemorrhaging

Uncontrolled bleeding results in 90% mortality within the first hour of injury on the battlefield and remains the leading cause of preventable death. Mortality associated with this type of trauma only increases over time as a result of prolonged evacuation time. ONR is developing a fibrin gauze product which will significantly improve the ability to stop blood loss following a vascular injury. A key factor in getting blood to clot is the conversion of the plasma protein fibrinogen into fibrin fibers. These fibers activate other clotting factors and are what give the clot strength and stability. Serious wounds can lead to rates of bleeding beyond the ability of natural clotting agents to control bleeding. The product being developed uses an innovative synthetic silica nanofiber material which can activate clotting via both the intrinsic and extrinsic pathways, Additionally, it

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does not generate heat, mimics the size and structure of natural fibrin strands, dissolves in the body to non-toxic by-products, and provides a flexible platform to facilitate application to wounds.

Transfusion Safety

Treating warfighters seriously injured on the battlefield often necessitates an emergency transfusion of blood to stabilize the patient. However, the potential to transfuse incompatible or blood tainted with harmful pathogens is very real. In order to prevent those transfusion threats, ONR is developing several technologies to improve the safe use of our "walking blood bank, including two separate point-of-care products; one to rapidly screen a donor's and recipient's blood type to confirm compatibility, and the other to determine whether the donor's blood is contaminated with harmful pathogens (bacteria, viruses, or parasites) prior to transfusion. The devices being developed are striving to be man-portable, easy to use, quick, extremely reliable, and function in extreme operational and environmental conditions.

These two products are based on fundamentally different technological concepts of automated analysis. The first product (screen for compatibility) employs fluorescence imaging cytometry. We are currently developing two pathogens detection capabilities, one using a ligand-fluoresence technique and the other a gold-nanorod optoacoustic technique to locate and identify the harmful pathogen(s). All three approaches can analyze blood with much smaller volumes of less expensive reagents, with greater accuracy and faster analysis times than the current technologies, with hands-off automation, and will include a more flexible array of blood analysis functions.

Blood Substitutes

ONR is developing two blood substitute product lines that currently show great promise. Firstly, a spray-dried plasma product is under development which can be easily reconstituted in the field and administered by corpsmen and physicians. Plasma not only serves to replace lost blood volume due to hemorrhage, but also provides coagulation factors as well that are essential to arrest uncontrolled bleeding. The dried plasma must be made to remain stable at ambient temperatures without the need for refrigeration. Also under development is a dried-plasma base to serve as a medium for infusible freeze-dried platelets. The objective of this portion of the research is to deterime the optimal formulation of plasma and platelets to attain maximum control of internal bleeding and to document the efficacy of this formulation.

Closed-Loop Systems

The closed-loop ventilation system will comprise two FDA-approved software algorithms to provide closed-loop-control (CLC) of a mechanical ventilation system specifically developed for en route treatment of trauma associated with hemorrhagic hypovolemia (blood loss) and burn shock. One algorithm will control mechanical ventilation based on blood oxygen saturation levels, monitored by pulse-oximetry (SPO2 blood oxygen content monitoring). The second algorithm includes the addition of positive end-expiratory-pressure (PEEP), which is required to ensure the lungs are adequately inflated (to prevent lung collapse). The algorithm will provide a PEEP of 5-15 cmH2O which has been found to be the range where a trauma patient can be safely managed for transport. Development of both algorithms has been completed and validated in a large animal model and clinical evaluations are currently in progress. An additional benefit of this approach is the reduced amount of oxygen required to maintain appropriate blood oxygen levels (due to a reduced need to maintain 100% oxygen for extended periods); this reduced oxygen requirement will reduce the medical logistics footprint.

The administration of vital fluids for trauma care requires considerable attention on the part of medical personnel. Too little fluid will not have the necessary effects (such as increasing blood pressure), too much can flood the lungs and do additional harm to the patient. The ability of medical personnel to provide critical emergency care can be severely limited by the labor intensive nature of vital fluid delivery to stabilize patients in need of critical care. Having a capability to automatically monitor and administer vital fluids to critical care patients is an absolute necessity in expeditionary operations. The closed-loop fluid (CLF) delivery system enables more robust and consistent critical care to warfighters with life-threatening injuries who are often at long distances from a fully-capable medical facility.

The CLF system is comprised two technology development efforts. First, a software algorithm designed to control fluid resuscitation was developed for the treatment of shock due to loss of blood and/or burns. This algorithm will be incorporated into the second effort, a PDA-type device that will provide decision-assist (DA) and fully automated control capabilities. Decision-assist means that the software will guide resuscitative efforts by providing individualized treatment recommendations to the corpsman based on the patient's physiological status; full automation will control resuscitation based on sensors directly attached to the unit from the patient. In DA mode, the system asks for manual input of injury and physiological data then provides treatment recommendations for the corpsman in the form of displays and specific directives. In automated mode, the system assumes management of the casualty. The algorithm was developed with expert clinical opinion and was subsequently validated in a large animal model of hemorrhagic shock.

The Automated Critical Care System (ACCS) will capitalize and leverage the work on the closed-loop fluid and ventilation systems. ACCS is a system-of-systems capability to provide physiologic monitoring and automatic intervention, fluid resuscitation, mechanical ventilation, supplemental oxygen therapy, fluid and drug therapy, casualty and fluid warming, and analgesia and anesthesia treatment. The ACCS will also be able to transmit patient parameters to a digital radio for transmission. The system will be capable of autonomous operation in performing 15 of the 17 (88%) required in-flight tasks.

Casualty Warming

ONR supported the development of the Patient Warming Device (PWD) to help maintain body temperature during Casualty Evacuation (CASEVAC) to a medical treatment facility. The PWD is a self-regulated, chemistry based appliqué for the prevention of hypothermia in susceptible casualties. It is an air activated chemistry based approach that requires no external power. The PWD is lightweight, compact, low-cost, disposable, and shelf-stable for extended periods of time. Self-regulation is achieved by a unique dual layer technology. It provides safe unattended operation and a stable temperature profile that is maintained for up to 8 hours. The appliqué is segmented; parts can be pulled off as needed for access to wounds. It is being demonstrated in a series of clinical trials against similar Commercial-Off-The-Shelf (COTS) devices. The PWD has successfully maintained a patient skin interface temperature of 40oC (104oF) for 8 full hours greatly surpassing the stability of other devices.

MEDICAL PLANNING

A key component of Naval expeditionary medicine is an adequate planning capability. This capability allows for the effective positioning and utilization of resources to increase the overall capacity for medical treatment in large, asymmetric theaters of operation. Developing proper modeling tools will enable medical planners and providers to determine ideal resource allocation as well as to gage the value of different interventions for controlling the spread of diseases amongst forces. The medical planning tool that has been developed

comprises three software development efforts; a modeling component to enable patient stream driven decisions, died-of-wounds algorithms for incorporation into an existing medical planning tool (Theater Medical Logistics Plus; TML+), and a crisis action planning module to extend the capability of the TML+ program. The combined effort will produce a module that affords a deployed medical planner a quantitative means to quickly assess options for the placement, staffing, and operation of a medical treatment facility network in a dynamic environment and decide prudent courses of action.

DIAGNOSTICS

The capability to provide an accurate, concise, and timely diagnosis on the battlefield is a daunting challenge to corpsmen, medics, and doctors alike. The typical equipment is too large and heavy to transport, demands excessive power requirements, is slow to provide results, and is difficult to operate and maintain in a hostile field environment.

Furthermore, providing the capability to diagnose and triage internal injuries as early as possible has the definite potential to save many more lives that would have been lost due to internal bleeding, pulmonary trauma, lung damage, and brain hematomas. The purpose is to provide far-forward medical care providers with a single medical diagnostic tool to rapidly assess the condition of the patient and triage accordingly. Currently this is planned will include x-ray, radar, ultrasound, and infra-red technologies into a man-portable, lightweight, compact, and ruggedized container. The utility of each technology to discern other than its traditional diagnostic capacity is currently being evaluated.

CONCLUSION

ONR's technology investments are providing warfighters the capability to plan, diagnose, treat, and transport battlefield injured rapidly and effectively from point-of-injury through transport to higher level care. These advancements will continue to increase survival, increase recovery from injury, and speed return to duty for personnel. Continued efforts strive to bring the full spectrum of medical capabilities to far-forward battlefields.